IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. BIONPHARMA INC., Defendant.	C.A. No. 3:21-cv-12870-MAS-DEA [redacted] *Document Filed Electronically*

BRIEF IN SUPPORT OF PLAINTIFF AZURITY PHARMACEUTICALS, INC.'S ORDER TO SHOW CAUSE FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION, AND OTHER EMERGENT RELIEF

Arnold B. Calmann
Katherine A. Escanlar
SAIBER LLC
One Gateway Center, 9th Floor
Newark, NJ 07102-5308
T: (973) 622-3333
abc@saiber.com
kescanlar@saiber.com

Attorneys for Plaintiff Azurity Pharmaceuticals, Inc.

Wendy L. Devine
Kristina M. Hanson
WILSON, SONSINI, GOODRICH & ROSATI P.C.
One Market Plaza
Spear Tower, Suite 3400
San Francisco, CA 94105-1126
Telephone: (415) 947-2000

Natalie J. Morgan
Evan Sumner
WILSON, SONSINI, GOODRICH & ROSATI P.C.
12235 El Camino Real
San Diego, CA 92130-3002
Telephone: (858) 350-2300

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

RULES

TABLE OF ABBREVIATIONS

'023 Patent	U.S. Patent No. 11,040,023
'008 Patent	U.S. Patent No. 9,669,008
'442 Patent	U.S. Patent No. 9,808,442
'987 Patent	U.S. Patent No. 10,154,987
'745 Patent	U.S. Patent No. 10,039,745
'868 Patent	U.S. Patent No. 10,772,868
'482 Patent	U.S. Patent No. 10,786,482
'621 Patent	U.S. Patent No. 10,918,621
ACE	Angiotensin converting enzyme
ANDA	Abbreviated New Drug Application
Azurity	Plaintiff Azurity Pharmaceuticals, Inc.
Bionpharma	Defendant Bionpharma Inc.
Bionpharma's ANDA	ANDA No. 212408
Bionpharma's ANDA Product	Product that is the subject of Bionpharma's ANDA No. 212408
Buckton	Declaration of Graham Buckton (filed herewith)
Epaned®	EPANED® (enalapril maleate) Oral Solution, 1 mg/mL
Ex.	Exhibits attached to the Declaration of Wendy L. Devine (filed herewith)
FDA	U.S. Food & Drug Administration
Patel	Declaration of Amit Patel (filed herewith)
PHE	Prosecution History Estoppel
POSA	Person of ordinary skill in the art
RTU	Ready-to-use
Stec	Declaration of Jeffery A. Stec, Ph.D. (filed herewith)

** Unless otherwise noted, all emphasis is added, all internal quotations and citations are omitted, and all "D.I." citations are to the docket in C.A. No. 21-12870 (D.N.J.).

Plaintiff Azurity,[1] a small specialty drug manufacturer, seeks a Temporary Restraining Order ("TRO") and Preliminary Injunction to enjoin its direct competitor defendant Bionpharma from inflicting imminent, irreparable harm on Azurity through the launch of Bionpharma's generic equivalent to Azurity's patented Epaned® product. The highly expedited nature of this application and the need for a TRO is a direct result of Bionpharma's failure to comply with and violation of Local Patent Rule 3.6(j) in order for it to escape producing the required documentation that would facilitate Azurity's evaluation of Bionpharma's actions. Because of Bionpharma's failure, Azurity only learned that Bionpharma requested that FDA convert its ANDA's tentative approval to a final approval when the FDA publicly disclosed that Bionpharma's request had been granted.

Local Patent Rule 3.6(j) mandates that a party having a pending ANDA application before the Food and Drug Administration ("FDA") "shall . . . (2) ***provide a copy of all correspondence between itself and the FDA pertaining to the ANDA application to each party asserting infringement . . . no later than seven days after the date it sends same to the FDA or receives same from the FDA***." Bionpharma did no such thing, despite requests from counsel asking for compliance. Instead, it simply ignored its obligation under that Rule. Bionpharma attempted to strategically position itself to launch its generic product without providing Azurity with the information to which it was entitled and that would have immediately disclosed the status of Bionpharma's ANDA application, which would have provided Azurity with a fair opportunity to respond that the Rule was designed to provide. *See* L. Pat. R., Explanatory Note

[1] Azurity is the successor-in-interest to Silvergate Pharmaceuticals, Inc. ("Silvergate"). [redacted]. Patel, ¶ 1. For simplicity, both Azurity and Silvergate are referred to herein as "Azurity."

for 2011 Amendments (ANDA filer was to "supply the parties with relevant communications with the FDA which concern the subject matter filed in the District Court. ***This is intended to keep the FDA and parties apprised of any proceedings that may impact ongoing litigation.***"). The effect of Bionpharma's subterfuge is palpable—had Azurity been provided with the required disclosures, it would have had more time to prepare and seek relief from the Court, but instead Bionpharma engineered the need for a race to the courthouse that imposes an enormous burden on Azurity and most importantly upon the Court. As a direct result of Bionpharma's attempted end run around the Local Patent Rules, Azurity is compelled to seek a TRO and Preliminary Injunction on short notice

Azurity will demonstrate that it meets the critical four-factor test for obtaining a TRO and preliminary injunctive relief. Here, Bionpharma's ANDA provides indisputable evidence that Bionpharma's ANDA Product will literally infringe at least claims 1-6, 10, 12-16, and 19 of the '023 Patent. If Bionpharma is allowed to launch before this infringement claim can be adjudicated, Azurity will face immediate irreparable harm to its long-term business, pipeline and R&D efforts, sales of other products for which the patented Epaned® product provides a gateway, in addition to price erosion, and loss of customers and market share. As Azurity and Bionpharma are direct competitors and Bionpharma's ANDA Product has been rated "AB" (meaning it's exchangeable by a pharmacy when a prescription for Epaned® is written), Bionpharma's ANDA Product will be substituted for Azurity's branded Epaned® product as the generic equivalent. Patel, ¶ 12.

Bionpharma has apparently received final approval from FDA, and the 30-month stay preventing launch of its ANDA Product ended in April. Unless Bionpharma is preliminarily enjoined, a launch by Bionpharma would cause Azurity significant irreparable harm.

Because Epaned® treats serious cardiac conditions, the public's best interests and the balance of hardships favors maintaining the current status quo, where Azurity continues to invest in educating providers on the benefits and safety of Epaned®—the one and only oral liquid enalapril formulation. For these reasons, Azurity requests that the Court issue a TRO and preliminary injunction.

I. BACKGROUND

A. AZURITY AND EPANED®

Azurity provides high-quality medicines to both children and elderly adults. Ex. 1 at 1; Ex. 2, ¶ 2. Azurity developed Epaned®, the first and only FDA approved RTU oral enalapril solution, to bring a safe, stable drug to these underserved patient populations. Ex. 1 at 1. Epaned® is an ACE inhibitor approved for treatment of hypertension in adults and children older than one month. Ex. 2, ¶¶ 21,26. Epaned® is also approved for the treatment of heart failure and asymptomatic left ventricular dysfunction. *Id*., ¶ 25.

Epaned®'s active ingredient is enalapril maleate. *Id.*, ¶ 24. Enalapril was initially approved by FDA in 1985 as an oral solid tablet. *Id*., ¶ 27. However, tablets are ill-suited for pediatric and elderly patients who often have trouble swallowing them. *Id*., ¶ 28. To overcome this issue, the enalapril tablets were compounded or crushed by mortar and pestle and reconstituted in diluent prior to administration. D.I. 1-1 at 5:50-62. Although compounding carried significant drawbacks—*e.g*., inaccurate and inconsistent dosing, cross-contamination, and inclusion of excess excipients present in solid tablets (but which are not necessary for a liquid dosage form)—it remained the best way to administer enalapril tablets to patients with difficulty swallowing for several decades. *Id*; Patel, ¶¶ 7, 39.

Azurity first attempted to address the compounding issue by developing a reconstituted powder formulation of enalapril (hereafter, "Epaned® Kit") in 2013. Ex. 2, ¶ 29; Patel, ¶ 40.

While Epaned® Kit was an improvement over compounding, it remained flawed. Epaned® Kit still required the pharmacist to mix powder with diluent, leaving room for dosage errors, contamination, and inconsistencies; and it was stable for only 60 days once reconstituted, meaning it could not be manufactured and distributed as a RTU solution. Ex. 3 at 78:22-79:6, 82:5-6.

Epaned® is the result of Azurity's significant R&D efforts and investment—[redacted]. Stec, ¶ 13. Because Epaned® is manufactured and supplied as an RTU oral solution, there is no need for reconstitution, compounding, or other manipulation prior to administration. This removes the risks previously associated with solid or powder forms of enalapril and enhances its stability and ease of use resulting in increased patient compliance. Ex. 3 at 78:22-79:6, 94:12-16; Patel, ¶ 7. Notably, Epaned® is stable for three years from the date of manufacture. Ex. 3 at 87:4-6.

B. THE '023 PATENT

The '023 Patent is titled "Enalapril Formulations" and claims priority to U.S. Patent Application No. 15/081,603 (now U.S. Patent No. 9,669,008, or "the '008 Patent"). D.I. 1-1. The '023 Patent claims oral liquid formulations of enalapril. Claim 1 of the '023 Patent is the sole independent claim and recites the following formulation:

> (1) A stable oral liquid formulation, consisting essentially of:
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
> (ii) a sweetener;
> (iii) a preservative, wherein the preservative comprises sodium benzoate, a paraben or mixture of parabens;
> (iv) water; and
> (v) optionally a flavoring agent;
> wherein the formulation is stable at about 5±3 °C. for at least 12 months; and
> wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

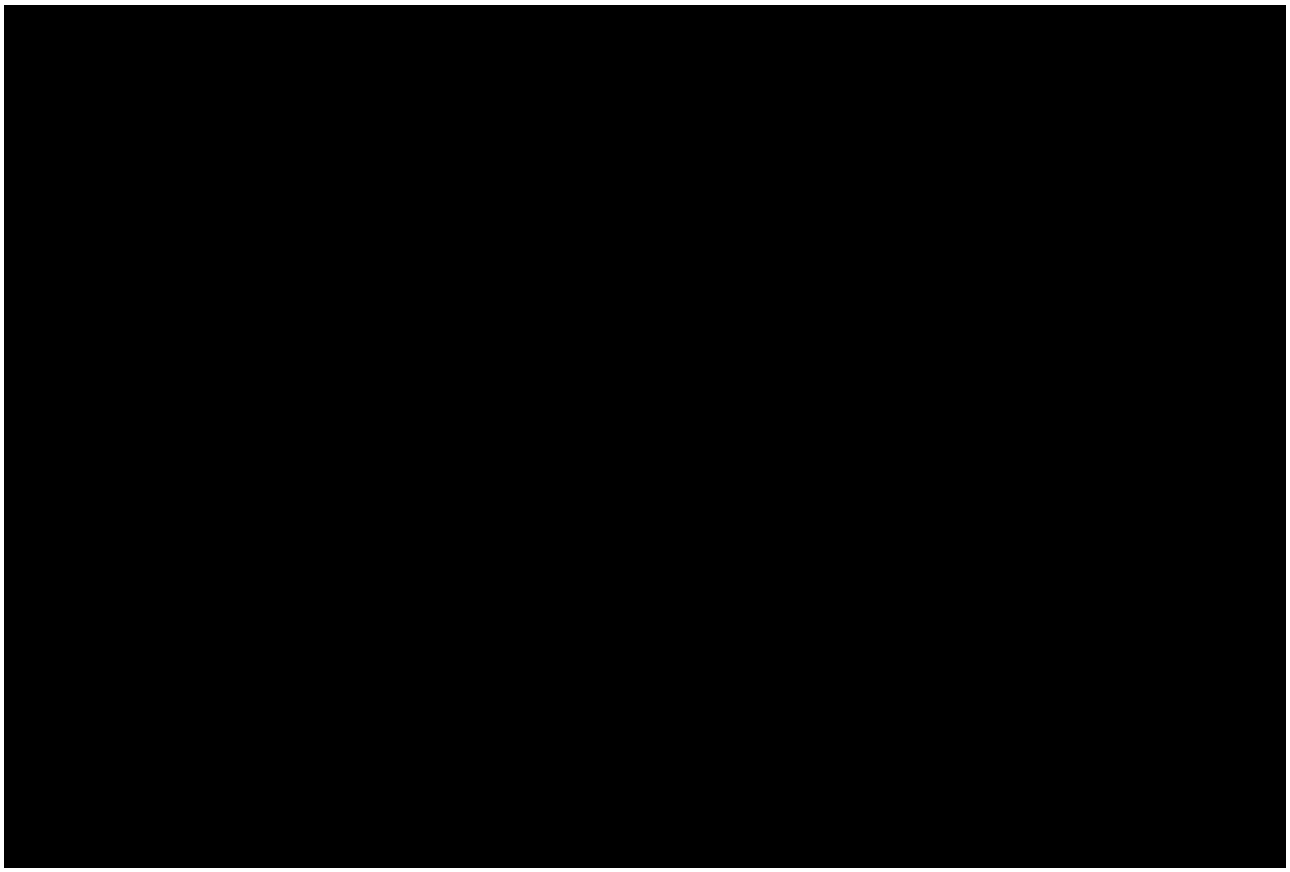
Claims 3 and 5 are dependent from Claim 1 and recite as follows:

(3) The stable oral liquid formulation of claim **1**, wherein the formulation is stable at about 5±3 °C. for at least 24 months.

(5) The stable oral liquid formulation of claim **1**, wherein the formulation maintains a pH between about 3 and about 4 for at least 12 months at about 5±3 °C.

C. BIONPHARMA'S ANDA PRODUCT

Bionpharma submitted ANDA No. 212408 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or importation of its generic version of Azurity's Epaned®. Ex. 2, ¶ 33. CoreRx, a contract manufacture, developed Bionpharma's ANDA Product. *Id.*, ¶ 39. The formulation of Bionpharma's ANDA Product is described in its ANDA and, in particular, is set forth in the composition statement submitted with the ANDA. According to that composition statement, the quantitative formulation of Bionpharma's ANDA Product is as follows:



Ex. 4 at BION-ESOL-00000231.

Bionpharma has represented to FDA that its ANDA Product is bioequivalent to Epaned®. Ex. 5 at 3. FDA granted tentative approval of Bionpharma's ANDA Product on December 28, 2020. Ex. 6. According to the public FDA website, Bionpharma's ANDA was granted final approval on August 10, 2021. *See*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212408.

D. PRIOR PROCEEDINGS BETWEEN THE PARTIES

On December 12, 2018, Azurity brought an action against Bionpharma for infringement of the '008 Patent, the '442 Patent, and the '745 Patent.[2] Thereafter, on June 7, 2019, Azurity

[2] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc*., C.A. No. 18-1962 (D. Del.).

brought an action against Bionpharma for infringement of the '987 Patent.[3] These actions were consolidated in C.A. No. 18-1962 and proceeded on the same schedule. A trial was conducted in February 2021 regarding the '745 and '987 Patents. Bionpharma only disputed infringement and did not challenge the patents' validity or raise any other defenses. The result of that case is on appeal before the Federal Circuit. On September 18, 2020, Azurity brought an action against Bionpharma for infringement of the '868 Patent, and on September 29, 2020 and March 4, 2021, filed amended complaints for infringement of the '428 and '621 Patents, respectively.[4] The Parties filed a Stipulation of Dismissal on May 17, 2021 pending the outcome of the decision on appeal in C.A. No. 18-1962.

Following appeal and dismissal of the prior proceedings, the USPTO issued the '023 patent and Bionpharma certified to FDA that it intends to launch the Bionpharma ANDA product prior to the expiration of the '023 patent. Azurity asserts a claim for infringement of the '023 patent in the present case.

II. LEGAL STANDARD

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008); *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, 967 F.3d 1339, 1345 (Fed. Cir. 2020). The factors for granting a temporary restraining order are the same. *Health Prof'ls & Allied Emps. AFT/AFL-CIO v. MHA, LLC,* No. 17-13301 (JMV), 2017 WL

[3] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 19-1067 (D. Del.).

[4] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.).

6550488, at *2 (D.N.J. Dec. 21, 2017). All four factors strongly favor granting preliminary injunctive relief to Azurity.

III. AZURITY IS LIKELY TO SUCCEED ON THE MERITS

Azurity is likely to succeed on the merits. Bionpharma's ANDA Product infringes at least claims 1-6, 10, 12-16, and 19 of the '023 Patent and Bionpharma cannot raise a meritorious question regarding the validity of those claims. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1338-40 (Fed. Cir. 2003).

A. BIONPHARMA'S ANDA PRODUCT INFRINGES CLAIMS 1 AND 3 OF THE '023 PATENT

Bionpharma cannot dispute that its ANDA Product literally meets all limitations of at least claims 1 and 3 of the '023 Patent. Claim 3 depends from claim 1. At trial in C.A. No. 18-1962, Bionpharma stipulated that its ANDA Product literally meets the following limitations of claim 3, as incorporated from independent claim 1:

Claim Limitation	Uncontested Fact[5]
stable oral liquid formulation	Ex. 2, ¶¶ 168, 204-205
about 0.6 to about 1.2 mg/ml enalapril or salt thereof	*Id.*, ¶ 169
water	*Id.*, ¶ 170
stable at about 5±3°C for at least 24 months	*Id.*, ¶¶ 171, 205
95% / 5% assay	*Id.*, ¶ 203

The only limitations of claim 3 that Bionpharma did not stipulate to relate to the sweetener, flavoring agent, and preservative limitations, as defined below. Bionpharma has represented to FDA that all three of these limitations are found in its ANDA Product, however.

[5] Bionpharma stipulated to these facts during trial in C.A. No. 18-1962 and is collaterally estopped from contesting such facts for the '023 Patent. *See Biogen Int'l GmbH v. Amneal Pharm. LLC*, 487 F. Supp. 3d 254, 258 (D. Del. 2020); *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006); *see also Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955, 959 (Fed. Cir. 2017) (regional circuit law governs issues of collateral estoppel).

1. Bionpharma's ANDA Product Meets the Sweetener Limitation

Claim 1, as incorporated by claim 3, requires "a sweetener." Bionpharma's ANDA composition statement discloses that its ANDA Product contains [redacted] Ex. 4 at BION-ESOL-00000231; § I.C., *supra*. The ANDA further specifies that both [redacted] function as a "sweetener" in the formulation. Ex. 4 at BION-ESOL-00000231. Indeed, the ANDA explains that [redacted] *Id.* at BION-ESOL-00000259, *see also* BION-ESOL-00000233, BION-ESOL-00000286. The '023 Patent defines sweeteners as "any compounds that provide a sweet taste," and specifically discloses both sucralose and sorbitol as sweeteners that may be used in an oral liquid formulation according to claim 1. D.I. 1-1 at 8:44-56, 9:43-10:4. Thus, either of the sucralose or sorbitol solution within Bionpharma's ANDA Product literally meets the "sweetener" limitation of claim 3.

2. Bionpharma's ANDA Product Meets the Flavoring Agent Limitation

Claim 1 of the '023 Patent, as incorporated in claim 3, recites "optionally a flavoring agent." To the extent a flavoring agent is required to infringe claim 3, Bionpharma's ANDA Product also literally meets this limitation. For example, Bionpharma's ANDA composition statement discloses that its ANDA Product contains artificial mixed berry flavor. Ex. 4 at BION-ESOL-00000231; § I.C., *supra*. The ANDA further specifies [redacted] Ex. 4 at BION-ESOL-00000231, BION-ESOL-00000247. Bionpharma's ANDA even compares the similarities of its ANDA Product to Epaned® and states that the [redacted] *Id.* at BION-ESOL-00000233. The '023 Patent discloses that a flavoring agent may be used to enhance the taste of the formulation, and

specifically discloses "mixed berry" as a flavoring agent that may be used in an oral liquid formulation according to claim 1. D.I. 1-1 at 17:61-18:14. Thus, the mixed berry flavor within Biopharma's ANDA Product literally meets the "flavoring agent" limitation of claim 1 as incorporated into claim 3.

3. Bionpharma's ANDA Product Meets the Preservative Limitation

Claim 1 of the '023 Patent, as incorporated in claim 3, recites a preservative that "comprises sodium benzoate, a paraben or mixture of parabens." The composition statement of Biopharma's ANDA discloses that its ANDA Product contains "methylparaben" and "propylparaben." Ex. 4 at BION-ESOL-00000231; § I.C., *supra*. Moreover, the ANDA specifies that methylparaben and propylparaben each function in the formulation as a "microbial preservative" due to their anti-microbial effectiveness and may function alone or together (*i.e.*, a mixture of parabens) as a preservative. Ex. 4 at BION-ESOL-00000231, BION-ESOL-00000262. Preservatives, according to the '023 Patent, include "anti-microbials, antioxidants, and agents that enhance sterility." D.I. 1-1 at 10:34-35. Indeed, methylparaben and propylparaben are both specifically disclosed as "exemplary preservatives" in the specification. *Id.* at 10:34-42. Thus, the methylparaben and propylparaben (*i.e.*, a mixture of parabens) within Bionpharma's ANDA Product literally meet the "preservative" limitation of claim 1 as incorporated in claim 3.

Accordingly, Bionpharma's ANDA Product literally meets all limitations of claim 3 of the '023 Patent.

B. BIONPHARMA'S ANDA PRODUCT INFRINGES CLAIM 5 OF THE '023 PATENT

Bionpharma also cannot dispute that its ANDA Product literally meets all limitations of claim 5 of the '023 Patent. At trial in C.A. No. 18-1962, Bionpharma stipulated that its ANDA Product literally meets the following limitations of claim 1, as incorporated in claim 5:

Claim Limitation	Uncontested Fact[6]
stable oral liquid formulation	Ex. 2, ¶¶ 168, 204-205
about 0.6 to about 1.2 mg/ml enalapril or salt thereof	*Id.*, ¶ 169
water	*Id.*, ¶ 170
stable at about 5±3°C for at least 12 months	*Id.*, ¶¶ 171, 205
95% / 5% assay	*Id.*, ¶ 203

The only limitations of claim 5 that Bionpharma did not stipulate to relate to the sweetener, flavoring agent, preservative, and pH stability limitation. Bionpharma has represented to the FDA that all four of these limitations are found in its ANDA Product, however. For the reasons explained above in Sections III.A.1-3, Bionpharma's ANDA Product meets the sweetener, flavoring agent, and preservative limitations.

1. Bionpharma's ANDA Product Meets the pH Limitation

Bionpharma's ANDA composition statement discloses that its ANDA Product has a pH upon release between 3.2 to 3.7 and a pH during stability between 3.2 to 3.7. Ex. 4 at BION-ESOL-00000299; § I.C., *supra*. Additionally, stability data submitted to FDA shows stability of the exhibit batches at 12 months between 3.3 to 3.4. Ex. 7 at BION-ESOL-00032006, 32010, 32012, 32014, 32016. Thus, Bionpharma's ANDA Product literally meets the limitation "wherein the formulation maintains a pH between about 3 and about 4 for at least 12 months at about 5±˚C." limitation of claim 5.

[6] Bionpharma stipulated to these facts during trial in C.A. No. 18-1962 and is collaterally estopped from contesting such facts for the '023 Patent. *See Biogen*, 487 F. Supp. 3d at 258; *Jean Alexander*, 458 F.3d at 249; *see also Allergan*, 681 F. App'x at 959 (regional circuit law governs issues of collateral estoppel).

C. CONSISTING ESSENTIALLY OF

Claim 1 of the '023 Patent claims a stable oral liquid formulation, "***consisting essentially of***" recited components. The Federal Circuit has interpreted the "consisting essentially of" transition as requiring the listed claim elements and allowing additional elements so long as they do not have a material effect on the basic and novel properties of the claimed invention. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998); *see also Endo Pharm. Inc. v. Actavis Labs. UT, Inc.*, 660 F. App'x 959, 965-66 (Fed. Cir. 2016) (affirming infringement of "consisting essentially of" claim where the ANDA product included an unrecited component that did not "play a material role" in the basic and novel properties of the claimed invention).

Bionpharma's ANDA Product indisputably includes all of the limitations of claim 1. The only elements listed in Bionpharma's ANDA Product that are not listed in claim 1 are (i) propylene glycol and (ii) hydrochloric acid/sodium hydroxide. Ex. 4 at BION-ESOL-00000231; § I.C., *supra*. Given that Biopharma's ANDA specifies that propylene glycol functions as a "co-solvent"[7] and that hydrochloric acid/sodium hydroxide function as "pH adjuster[s]," neither ingredient is material to the basic properties and novelty of the claimed invention of claim 1. *Id.* at BION-ESOL-00000231. Bionpharma is estopped from arguing to the contrary based on prior representations made in C.A. No. 18-1962.

Accordingly, there is a likelihood of success on the merits with respect to infringement of at least claim 1 of the '023 Patent.

---

[7] Bionpharma's ANDA also specifies that propylene glycol functions to provide "palatability." *See, e.g.*, *id.* at BIOL-ESOL-00000265. To the extent propylene glycol is determined material to the basic and novel properties of the claimed invention of claim 1, the propylene glycol within Bionpharma's ANDA Product literally meets the "optionally a flavoring agent" and/or "sweetener" limitation of claim 1.

D. BIONPHARMA'S ANDA PRODUCT INFRINGES CLAIMS 2, 4, 6, 10, 12-16, AND 19 OF THE '023 PATENT

Bionpharma cannot dispute that its ANDA Product literally meets all limitations of claims 2, 4, 6, 10, 12-16, and 19 of the '023 Patent. Each of these claims depend from claim 1 and contain limitations requiring stability for 18 months, stability for 3 months, a sweetener that is sucralose, a flavoring agent, 1.0 mg/ml of enalapril or a pharmaceutically acceptable salt or solvate thereof, a preservative that is a mixture of parabens, the mixture of parabens is methylparaben and propylparaben, the mixture of parabens is present in a specific amount. As discussed above, Bionpharma's ANDA product indisputably meets all of these claim limitations.

E. BIONPHARMA CANNOT RAISE A SUBSTANTIAL QUESTION OF VALIDITY

Bionpharma is unlikely to raise any substantial question concerning the validity of the '023 Patent. *Oakley*, 316 F.3d at 1339-40. Notably, in C.A. No. 18-1962, Bionpharma did not challenge the validity of the '745 and '987 Patents.[8] *See* § I.D., *supra*. And though Bionpharma challenged the validity of the '868, '482, and '621 Patents, those same arguments would fail to raise a substantial question of validity if made here and are inapplicable to the claims of the '023 patent. *See, infra*, § III.F.[9]

The '023 Patent is presumed valid and at trial Bionpharma bears the burden of proving otherwise by clear and convincing evidence. Its "very existence" satisfies Azurity's burden to show a likelihood of success with respect to validity unless Bionpharma produces persuasive

[8] The '745 and '987 Patents are within the same patent family as the '023 Patent and claim liquid formulations of enalapril.

[9] While Bionpharma challenged the validity of the '868, '482, and '641 patents at the preliminary injunction stage, the parties never exchanged contentions or engaged in discovery regarding these patents before dismissing subject to the decision on appeal.

evidence otherwise. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001). Bionpharma cannot identify any such "persuasive evidence."

Below, Azurity addresses the contentions set forth in Bionpharma's notice letter regarding the '023 patent.

1. The Claims of the '023 Patent Are Not Obvious

Bionpharma's allegations regarding obviousness cannot meet its burden of "persuasive evidence." *Id.* "Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination." *Unigene Labs., Inc. v. Apotex, Inc.,* 655 F.3d 1352, 1360 (Fed. Cir. 2011).

In its notice letter, Bionpharma alleged that the claims of the '023 patent are obvious over the prior Epaned® Kit package insert, in view of Ip and Brenner, FDA Stability Guidance, and U.S. Patent No. 8,568,747 (the "'747 patent"). Patel, ¶ 10. The Epaned® Kit package insert does not disclose (nor do any of the other references) an oral liquid formulation of enalapril with the claimed stability ***of at least 12-24 months***, as required by each of the claims. The Epaned® Kit was ***not*** a RTU product, but had to be reconstituted by the pharmacist, and once reconstituted in liquid, was stable for only 60 days. Ex. 3 at 78:22-79:6, 82:5-6. The '747 patent relates to the Epaned® Kit and describes and claims enalapril powder formulations for reconstitution. Indeed, the Epaned® Kit had a stability specification requiring only 90% of the enalapril to remain during storage—not the 95% of the claims. *Id.* at 85:6-9. Likewise, the '747 patent describes the kit as having this same, lesser stability profile: "[s]table as used herein refer to enalapril oral liquid compositions having at least about 90% enalapril and 5% or less total impurities or substances at the end of a given storage period."

Neither Ip and Brenner nor the FDA Stability Guidance describe any enalapril formulations, and neither provides any motivation or guidance to convert the Epaned® Kit into a stable oral formulation.

Bionpharma has not identified any evidence of a motivation to modify the Epaned® Kit formulation by combining any teaching of the prior art to arrive at the claims of the '023 patent, let alone cite evidence of a reasonable expectation of success in doing so. Indeed, a POSA would not have been motivated to modify the Epaned® Kit into an RTU liquid formulation in the first place. Enalapril was available in tablet form and made into liquids only through compounding (discussed above) for ***decades*** prior to the introduction of Epaned® Kit. Thus, a person of skill in the art in March 2016 would have recognized that Epaned® Kit (approved in 2013) was the best possible solution. Buckton, ¶ 17. Notably, Ip and Brenner published in 1987—yet Bionpharma does not point to any evidence that, in the decades between 1987 and the 2016 priority date, anyone successfully applied Ip and Brenner to achieve a long-term, ready to use, stable formulation of enalapril. *See Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1359 (Fed. Cir. 2013) (finding the 22 years between the relevant prior art and the claimed invention "speaks volumes to . . . nonobviousness"); Buckton, ¶ 18. In reality, prior to the invention, no one ever created ***any*** stable, RTU oral liquid formulations of enalapril.

Bionpharma's obviousness contention is entirely based on hindsight and a misreading of the prior art, and thus cannot meet the clear and convincing evidence standard.

2. The Claims of the '023 Patent Are Enabled

"Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions." *Invitrogen Corp. v. Clontech Labs. Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005). The claims require a formulation that is stable for up to 24 months, and explicitly defines stability as a formulation that "has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances." *E.g.*, D.I. 1-1 at claim 1. The specification instructs that the amount of impurities is dependent on the pH of the formulation. *Id.* at 14:9-59. Using this information, a POSA could determine how to make and use the claimed inventions. Buckton, ¶¶ 23-24.

Bionpharma's enablement discussion in its notice letter is premised on legally and factually incorrect contentions. For example, Bionpharma faults the specification for not including a working example of every single formulation within the scope of the claims—thereby redefining the law to require every potential formulation to be recited and tested in the specification—that is not the legal standard for enablement. Bionpharma also incorrectly characterizes the scope of the claims. As discussed above, the specification's disclosures inform a POSA how to create the genus of stable, liquid formulations of enalapril recited in the claims. The notion that a POSA would require years' worth of stability testing on any of these formulations, let alone innumerate formulations, is also wrong. It would be a simple and routine matter for a POSA to practice the full scope of the claims. Moreover, the claims of the '023 patent are not of enormous breadth as Bionpharma contends—especially when they are viewed from the perspective of a person of skill in the art who could readily ascertain appropriate concentrations of excipients (including from the guidance in the specification regarding such concentrations).

There is no substantial question that the claims of the '023 patent are adequately enabled. *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 659-663 (E.D. Tex. 2017) (claims were enabled where the evidence showed the quantity of experimentation necessary was routine and the specification provided direction and guidance in light of the description, incorporated references, and working examples).

3. The Claims of the '023 Patent Are Described by the Specification

The specification of the '023 patent recites a limited genus of oral liquid formulations with certain stability properties. The specification contains ample written description for precisely such formulations, including reference to the fact that the formulation ***may optionally*** contain a buffer. *See, e.g.*, D.I. 1-1 at 13:58-59 ("In some embodiments, the oral liquid

formulation comprises a buffer."); Buckton, ¶ 24. Bionpharma's notice letter faults the specification for not including examples of such formulations—that contention is contrary to Federal Circuit law which states that a specification need not include any working examples to provide adequate written description, let alone a working example of each and every embodiment. *Alcon Research Ltd. v. Barr Labs.*, Inc., 745 F.3d 1180, 1190-91 (Fed. Cir. 2014). The law recognizes that claims reciting a genus are adequately described where the specification discloses either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that POSA can visualize or recognize the members of the genus. *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991, 994-95 (Fed. Cir. 2017); *Alcon*, 745 F.3d at 1190-91. Here, the specification discloses both.

Accordingly, there is a likelihood of success on the merits with respect to validity of the '023 Patent.

F. CLAIM PRECLUSION DOES NOT APPLY

The claims of the '023 patent are meaningfully different in scope from the claims of the patents in the first litigation. "[W]here different patents are asserted in a first and second suit, a judgement in the first suit will trigger claim preclusion ***only*** if the scope of the asserted patent claims in the two suits is ***essentially the same***." *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018) (emphasis added). Bionpharma's argument that the same patent rights that were involved in the earlier actions are involved in this action is sophistry given its own admission that claims of the '023 Patent "do not explicitly require[] a buffer component." D.I. 8-1 at 4. Although there are several differences in claim limitations, the absence of a "buffer limitation" in particular, dramatically changes the scope of the claims of the '023 Patent from those previously asserted in the first litigation, and thus the claims cannot be "essentially the same."

Likewise, the scope of the preservative limitation is meaningfully different. In the prior case, the claims of the asserted patents all literally required a formulation that contained sodium benzoate. In the claims of the '023 patent, however, the preservative can be "sodium benzoate, a paraben, or a mixture of parabens." D.I. 1-1 at claim 1. This is also an indisputable difference in scope.

These differences in claim scope are particularly meaningful because they negate the non-infringement arguments that Bionpharma made in prior litigation. Specifically, Bionpharma argued that it's ANDA product did not contain a buffer or sodium benzoate. Neither of those elements are required by the claims asserted here.

IV. ABSENT INJUNCTION, AZURITY WILL BE IRREPARABLY HARMED

Bionpharma is imminently poised to launch its generic equivalent to Epaned® into the market. It has received final approval by FDA, and the 30-month stay preventing launch of its ANDA Product ended in April.[10] Unless Bionpharma is preliminarily enjoined, a launch by Bionpharma would cause Azurity significant irreparable harm.

Direct Competition. As Azurity and Bionpharma are direct competitors, Bionpharma's ANDA Product will likely be substituted for Azurity's branded Epaned® product as the generic equivalent. Patel, ¶12; Stec, ¶¶ 67-69. In instances "[w]here two companies are in competition with one another, the patentee suffers the harm – often irreparable – of being forced to compete against products that incorporate and infringe its own patented inventions." *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Circ. 2013); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012). The irreparable harm caused by Bionpharma's direct competition is exacerbated by the fact that (i) Epaned® currently enjoys

[10] Azurity filed its first complaint against Bionpharma on December 12, 2018 which triggered a 30-month stay of FDA approval of Bionpharma's ANDA Product that expired on April 30, 2021. *See* § I.D, *supra*; Exs. 8, 9.

100% of the RTU liquid enalapril market and thus, Azurity would lose its market exclusivity following Bionpharma's launch;[11] and (ii) Azurity is a small specialty drug manufacturer and Epaned® is its flagship product. Stec, ¶¶ 67-69; Patel, ¶¶ 5, 8, 13; *see, e.g.*, *Metalcraft of Mayville, Inc. v. Toro Co.*, No. 16-C-544, 2016 WL 4076894, at *4 (E.D. Wis. Aug. 1, 2016), (where patentee previously owned 100% of the market, direct competition and loss of exclusivity "suggest[s] strongly the potential for irreparable harm"); *see also QBAS Co. v. C Walters Intercoastal Corp.*, No. 10-406, 2010 WL 7785955, at *12 (C.D. Cal. Dec. 16, 2010) (given "relatively small size of [company], losses this great can be devastating").

Harm From Bionpharma's Lower Priced Generic. Bionpharma's ANDA Product will almost certainly be priced much lower than Epaned®, both because Bionpharma does not have to [redacted] Azurity invested to develop, commercialize, and obtain FDA approval for Epaned®, and because third-party payor plans generally default to dispensing the lowest priced drug. Patel, ¶ 12; Stec, ¶ 70. Thus, when a physician writes a prescription for Epaned®, Bionpharma's proposed lower-cost generic will be substituted for Epaned®. Patel, ¶ 11.

As a result, Azurity expects to rapidly lose most of its market share which would reduce total Epaned® revenue substantially. Patel, ¶¶ 13, 16; Stec, ¶¶ 67-69. Moreover, there is no expectation that Epaned®'s market share and revenue would "bounce back" if Bionpharma's ANDA Product were later removed from the market.[12] For example, even if Bionpharma is only

[11] Azurity brands Epaned® as being ***the first*** and ***the only*** FDA approved RTU liquid enalapril formulation. Patel, ¶ 7; Stec, ¶ 14. If Bionpharma launches, Azurity would not only lose its ability to differentiate Epaned® as ***the only*** such product, but it would also incur significant costs to (potentially permanently) rebrand Epaned® to reflect the loss of that status. Patel, ¶¶ 32-36.

[12] As explained by Dr. Stec, the often-cited Plavix case history is inapplicable to the present facts. Stec, ¶¶ 91-103.

on the market for a single day, Bionpharma could flood the market with an entire year's volume or more of its ANDA Product before it exits the market, requiring Azurity to compete with (and lose market share/revenue to) Bionpharma's generic for months thereafter. Patel, ¶ 18; *see also Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 658 (D. Del. 2010) (finding irreparable harm from lost market share and revenue due to generic "inventory overhang"); *see also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008).

Additionally, Bionpharma's lower-priced ANDA Product would almost certainly exert a downward pressure on the price of Epaned®. Patel, ¶ 16; Stec, ¶¶ 70, 81-82. No matter how Azurity reacts to such pricing pressures [redacted], Bionpharma's lower-priced ANDA Product would result in de-facto price erosion and decreased revenue because the prescriptions would still be filled for the lower-priced generics. Patel, ¶ 16. Moreover, should Bionpharma's ANDA Product be removed from the market, it would be difficult to reverse [redacted] due to contractual obligations and patient expectations.[13] Patel, ¶¶ 16, 18-19; Stec, ¶ 82. Such irreversible effects from generic price erosion pressures would indeed result in irreparable harm to Azurity. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006); *Abbott Labs. v. Sandoz,*

[13] If Azurity were to [redacted] following removal of Bionpharma's proposed ANDA Product, many patients would likely turn to compounded drugs which are priced similarly to the generic options. Patel, ¶¶ 19, 43; Stec, ¶¶ 73-74. However, Azurity would not wish for patients to revert to inferior compounded drugs simply because of pricing issues. Patel, ¶¶ 19, 47. Thus, Azurity would likely face substantial pressure to [redacted].

Inc., 500 F. Supp. 2d 807, 844-45 (N.D. Ill. 2007); *Hoffmann-La Roche Inc. v. Cobalt Pharm. Inc.*, No. 07-4539 (SRC), 2010 WL 4687839, at *11-12 (D.N.J. Nov. 10, 2010).[14]

Reversion to Compounded Drugs and Costs of Reeducation. Azurity has made significant efforts to educate healthcare providers and patients on the benefits (efficacy and safety) of Epaned® product over compounded drug formulations. Patel, ¶¶ 19, 38-42; Stec, ¶ 82. But if Bionpharma launches, Azurity has the choice of either (i) continuing its education efforts which would likely promote greater sales of Bionpharma's infringing ANDA Product because of automatic generic prescription substitutions, or (ii) discontinuing its educational efforts because of the reduced revenues and the reduced likelihood of returns on those efforts. Patel, ¶¶ 23, 45-46. The latter would ultimately negatively impact patients, as fewer healthcare providers would communicate to their patients the benefits of Epaned® relative to compounded options. Patel, ¶¶ 39-41, 45-48; Stec, ¶¶ 77, 82. Moreover, even if Bionpharma's ANDA Product was later removed from the market, Azurity would incur significant costs to re-educate doctors and patients regarding the benefits of Epaned®. Such costs would be in addition to the losses suffered while Bionpharma was on the market. Patel, ¶ 46; Stec, ¶ 74. *See Everett Labs., Inc. v. Breckenridge Pharm., Inc.*, 573 F. Supp. 2d 855, 868 (D.N.J. 2008) (recognizing such a decision as a "Hobson's choice" for branded pharmaceutical companies).

Harm to Azurity's Other Cardiovascular Products. Azurity uses Epaned® [redacted]. Patel, ¶¶ 21-25. Thus, with

[14] Azurity faces other pricing-related harms that would be incredibly difficult and costly to reverse, such as loss of preferred formulary status and formulary tier for Epaned®. Patel, ¶¶ 14-15. Courts have consistently recognized that exactly such harms are often irreparable due to the "complex pricing scheme" in the pharmaceutical space. *Sanofi-Synthelabo*, 470 F.3d at 1382; *Abbott*, 500 F. Supp. 2d at 844-45; *Hoffmann*, 2010 WL 4687839 at *11–12.

any scale-back in educational efforts on Epaned®, Azurity's personnel will have significantly fewer opportunities to promote and sell its other cardiovascular products, [redacted]. Patel, ¶ 24; Stec, ¶ 77; *see also Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1337 (Fed. Cir. 2012) (lost sales of "tag-along products" support a finding of irreparable harm).

Loss of R&D Opportunities and Workforce Reductions. Lost sales and revenue would result in significant harms to Azurity's R&D pipeline and workforce. Even a short period of Bionpharma's generic entry may result in: [redacted]. Patel, ¶¶ 27-31; Stec, ¶¶ 76, 78-80; *see also Hoffmann*, 2010 WL 4687839 at *12 (reduction in workforce is irreparable harm); *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 609 F. Supp. 2d 786, 811-12 (S.D. Ind. 2009) (loss of research opportunities is irreparable harm).

Causal Nexus. An injunction is proper because a causal nexus exists between Bionpharma's infringement and Azurity's irreparable harm – *i.e.*, there is "some connection between the patented features and demand for the infringing product." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 639, 641 (Fed. Cir. 2015). Here, the patented features of the '023 Patent are embodied in Epaned®, and Bionpharma's ANDA Product infringes that patent. The '023 Patent is key to providing a suitable, RTU oral liquid enalapril formulation for those patients for whom conventional solid dosage forms are unsuitable. Indeed, the increased sales and profitability of the RTU Epaned® product (when compared to Epaned® Kit) result from its patented features which provide a desired level of safety and efficacy – as opposed to simply

being a function of marketing. Ex. 3 at 88:14-21, 103:13-20, 104:17-105:3, 108:20-109:5; *see, e.g.*, *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017); *Covidien Sales LLC v. Ethicon Endo-Surgery, Inc.*, No. 14-917, 2014 WL 5242872, at *12 (D. Conn. Oct. 15, 2014).

The imminent harm to Azurity is also directly tied to Bionpharma's infringement. Bionpharma has specifically utilized patented features in obtaining approval of its ANDA Product, thereby capitalizing on the goodwill of Azurity's pioneering (and patented) efforts to develop the first RTU liquid formulation of enalapril. Patel, ¶ 12; Stec, ¶ 53. Each of the irreparable harms discussed above will thus be a direct result of Bionpharma targeting doctors and patients with a lower cost, generic version of Epaned® that these doctors and patients would only utilize based on its association with Epaned®. *See Mylan Institutional*, 857 F.3d at 872-73 (causal nexus shown where defendant could not make its product without infringing the patents).

V. BALANCE OF HARDSHIPS FAVORS AZURITY

Azurity's harm will be much greater absent an injunction than the harm to Bionpharma if an injunction is granted. Requiring Azurity to compete against its own patented invention, with the resultant harm described above, places a substantial hardship on Azurity. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1156 (Fed. Cir. 2011); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 09-4638, 2010 WL 2516465, at *11 (D.N.J. June 14, 2010); Stec, ¶ 81. Moreover, it is well settled that the purpose of a preliminary injunction is to preserve the status quo and protect the respective rights of the parties pending a merits determination. *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 863 (Fed. Cir. 1987); *Abbott*, 544 F.3d at 1362. Issuing an injunction now would impose little consequence to Bionpharma because it has not yet launched its ANDA Product, and it would not lose its first-filer exclusivity. Stec, ¶¶ 87-89. Thus, the balance of the harms tips in favor of Azurity. *See, e.g.*, *Research Found.*, 723 F. Supp.

2d at 661 (even if preliminary injunction granted against first filer, the mere "time-shifting" of revenues from 180-days of exclusivity does not tip balance of harms in favor of generic defendant).

VI. PUBLIC INTEREST WEIGHS IN FAVOR OF PRELIMINARY INJUNCTION

Finally, public interest also weighs in favor of granting a preliminary injunction. To begin, the public has a significant interest in protecting patentee's right to exclude, for without which, incentives for research and development are lost. *Sanofi*, 470 F.3d at 1383-84; *Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, No. 05-5727, 2008 WL 1722098, at *12 (D.N.J. Mar. 28, 2008).

[redacted]. Additionally, if Bionpharma launches, and its ANDA Product is subsequently removed from the market, patients may resort back to less safe and less effective compounded formulations of enalapril. This could be potentially very harmful to doctors and patients who have become accustomed to using the RTU formulation of Epaned®. Patel, ¶¶ 19, 43-45, 47-48. Lastly, even if Bionpharma is prevented from selling its ANDA Product, Azurity has the capacity to fully meet patient demand with its Epaned® product. Patel, ¶ 49. In cases such as this one, where Azurity is practicing its invention and can meet consumer demand, "the public interest nearly always weighs in favor of protecting property rights." *Apple Inc.*, 809 F.3d at 647.

VII. THE COURT SHOULD ORDER EXPEDITED DISCOVERY

Azurity respectfully requests certain expedited discovery in order to further explore the irreparable harm alleged herein. At the very least, Bionpharma should produce all FDA correspondence to date regarding its ANDA. Further, Azurity seeks information related to irreparable harm, including, for example, Bionpharma's launch plans, forecasting and pricing. As discussed herein, it appears that a Bionpharma launch may be imminent, and Azurity expects Bionpharma to set a price that will significantly disrupt the market causing Azurity irreparable

harm. Discovery into these facts will allow Azurity to brief the issues in more detail for the Court's consideration. Moreover, to the extent that Bionpharma requests a bond, discovery regarding Bionpharma's forecasting, pricing, and launch plans are directly relevant to the amount of that bond. In light of the circumstances, such discovery is necessary and appropriate. *See Kone Corp. v. Thyssenkrupp USA, Inc.*, No. 11-465-LPS-CJB, 2011 WL 4478477, at *6 (D. Del. Sept. 26, 2011) (granting expedited discovery where there was a pending motion for preliminary injunction); *Commissariat A L'Energie Atomique v. Dell Computer Corp.*, No. 03-484-KAJ, 2004 WL 406351, at *1 (D. Del. Mar. 3, 2004) (granting expedited discovery for a preliminary injunction motion regarding patent infringement).

VIII. THE COURT SHOULD ORDER COMPLIANCE WITH THE LOCAL RULE AND EXPEDITED DISCOVERY

Azurity respectfully requests limited expedited discovery in order to explore the irreparable harm alleged herein. Apart from the discovery being requested, as demonstrated herein and as set forth in the Order to Show Cause herein, Bionpharma has an obligation to produce communications with FDA pursuant to L. Pat. R. 3.6(j). Bionpharma should produce all FDA communications to date regarding its ANDA, and should continue to comply with its obligation to do so as set forth in the Order to Show Cause.

Further, information sought to be uncovered relating to irreparable harm includes for example, Bionpharma's forecasting and pricing, the imminent nature of its launching of the ANDA product, and related discovery. Azurity expects Bionpharma to set a price that will significantly disrupt the market causing Azurity irreparable harm. Discovery into these facts will allow Azurity to present a fuller factual record to the Court in advance of the return date of the Order to Show Cause. In light of these circumstances, such discovery is necessary and appropriate. *See*, *Commissariat*, 2004 WL 406351 at *1 (granting expedited discovery for a preliminary injunction motion regarding patent infringement).

Accordingly, we respectfully request that the Court enter the Order to Show Cause and grant expedited discovery proceedings in connection therewith.

IX. CONCLUSION

For the foregoing reasons, Azurity respectfully submits that this Court should grant Azurity's Motion for a Temporary Restraining Order and Preliminary Injunction.

Dated: August 19, 2021

Respectfully submitted,

Saiber LLC
Attorneys for Plaintiff
Azurity Pharmaceuticals, Inc.

/s/ *Arnold B. Calmann*
Arnold B. Calmann
Katherine A. Escanlar
One Gateway Center, 9th Floor
Newark, NJ 07102-5308
T: (973) 622-3333
abc@saiber.com
kescanlar@saiber.com

OF COUNSEL:

Natalie J. Morgan
Evan Sumner
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real, Suite 200
San Diego, CA 92130-3002
(858) 350-2300
nmorgan@wsgr.com
esumner@wsgr.com

Wendy L. Devine
Kristina M. Hanson
WILSON SONSINI GOODRICH & ROSATI
One Market Plaza, Spear Tower, Suite 3300
San Francisco, CA 94105
(415) 947-2000
wdevine@wsgr.com
thanson@wsgr.com